

Attorney Docket No. P63142US1
Application No. 09/806,509

Amendments to the drawings:

Figures 2A and 2B, as amended in accordance with the Office Action, are presented in the drawings Replacement Sheet (Appendix I, *infra*), in place of the corresponding figures currently of record.

Attachment:

Replacement Sheet.

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Remarks/Arguments:

The specification is amended, hereby, to be commensurate with the amendments to the drawings, set forth above.

Amended drawing figures are submitted, herewith, as explained above.

Claims 37-56, presented hereby, are pending..

Claims 23-36 stand withdrawn, pursuant to restriction.

Claims 1-22 are canceled, without prejudice or disclaimer.

New claims 37-48 and 51-56 correspond to claims 1-3, 6-14, and 16-22, respectively, and new claims 49 and 50, together, correspond to claim 15, amended to more clearly define the instant invention, and, so, resolve the issues raised in the §112, ¶2, rejection (discussed below).

According to the Office Action, the subject application fails to comply with the Rules governing biological sequence disclosures. Specifically, it is alleged that sequence identifiers are missing for the nucleic acid sequences shown in application Figure 3. The Office Action is incorrect.

None of the nucleic acid sequences presented in Figure 3 contains at least ten nucleotides, and, so, they require neither sequence identifiers nor inclusion in the Sequence Listing. 37 CFR 1.821(a).

The drawings' objection is overcome, as required in the Office Action, by submitting the replacement drawing sheet (Appendix I, *infra.*), which amends Figure 2, as set forth above.

Claims 17-22 were rejected under 35 USC 101 for allegedly being non-statutory use claims i.e., for allegedly failing to set forth any method steps. Reconsideration is requested.

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The rejected claims are amended, hereby, as new claims 52-56. The new claims are directed to a "method of using a kit" and include the affirmative method steps

- measuring at least one of a level or biological activity of a transcription product and/or a translation product of (i) the cystatin C gene or (ii) a polymorphic variant of the cystatin C gene in at least one sample of cerebrospinal fluid from the subject; and
- comparing the at least one measured level or biological activity with a corresponding control from a non-Alzheimer's-diseased individual.

Accordingly, new claims 52-56, which replace rejected claims 17-22, respectively, contain the requisite method steps in order to satisfy the requirements of §101. Withdrawal of the rejection appears to be in order.

Claims 1-22 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Reconsideration is requested in view of the changes to the claims effected, hereby, taking injunction with the following remarks.

The present claims reflect changes to the rejected claims that address, and resolve, the alleged instances of indefinite claim language set forth in the statement of rejection, except the alleged instance set forth in item 12, i.e., the language "diagnosing or prognosing."

Reciting "diagnosing or prognosing" is allegedly indefinite because "diagnosing" allegedly means the same as "prognosing." The allegation is incorrect, as the two terms have well known different meanings, as evidenced by the different definitions found in diagnosis: Definition and Much More from Answers.com and prognosis: Definition and Much More from Answers.com, both available online (print outs provided, herewith, in Appendix II, *infra*). While claims are to be given their broadest reasonable interpretation during prosecution, the definition of claim terminology given

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by the Examiner cannot be different than would be given by one of ordinary skill in the art. *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir. 1999).

Moreover, concerning item 9 in the statement of rejection, the word "increase" defines the measured "level or biological activity" relative to that of a control. Accordingly, reciting "increase" does not render the claims indefinite.

Moreover, examples of increases can be found in application Table 5 and the accompanying text, at page 39, 1st ¶. Support is also found in application Example 1.

The precise amount of the "increase" is irrelevant, as this reflects concern about the scope of the language at issue, which has no bearing on whether the term is indefinite under § 112, ¶2, since claim "breadth is not to be equated with indefiniteness." *In re Miller*, 169 USPQ 597, 600 (CCPA 1970). Nevertheless, the claims are rewritten, hereby, to more clearly define this aspect of the invention—including replacing "increase" with "elevated," as used in the present specification (paragraph bridging pages 7 and 8).

For the foregoing reasons, withdrawal of the rejection under § 112, ¶2, appears to be in order.

Claims 1-16 were rejected under 35 USC 112, first paragraph, as allegedly lacking enablement. Reconsideration is requested, in view of the changes to the claims effected, hereby, taken in conjunction with the following remarks.

Contrary to allegations contained in the statement of rejection, the present specification provides detailed teachings for practicing the presently claimed invention, for example, in specification Examples 1-3. This rebuts the allegation that the inventors were in possession of only

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an idea of the presently claimed invention; the examples clearly demonstrate that applicants had both possession of both the idea of the presently claimed invention and the means, i.e., enablement, necessary to achieve the idea. Invention involves both the *idea* of the invention as well as the *means* to achieve the desired idea. *In re Hoffman* 37 USPQ 222 (CCPA 1938).

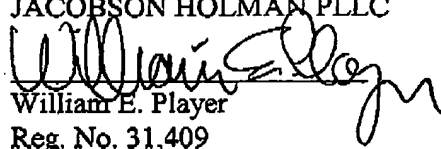
Note is taken that the rejection (under item 22 on page 8 of the Office Action) alleges "two sets of the results show (1) not significantly elevated concentration of cystatin C protein in AD samples (Table 1, . . .) and (2) significantly higher concentration of cystatin C in AD (Table 2 . . .) as compared to healthy controls and other diseases." However, on page 33 et seq., the present specification teaches "significantly higher CSF levels of cystatin C were found in AD patients than in either normal control subjects or patients with other non-AD neurological and psychiatric disorders as shown in Table 1." Thus, the interpretation given in the rejection is contradicted by the present specification.

Favorable action is requested.

Respectfully submitted,

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APPENDIX I
(Replacement Sheet of Drawings)

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APPENDIX II
(Supporting Documents)

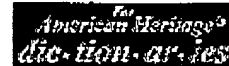
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diagnosis technique (in medicine)

diagnosis technique (in medicine)

Dictionary



di·ag·no·sis (dī'ag-nō'sis)

n., pl. -ses (-sēz).

1. *Medicine.*
 - a. The act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory data.
 - b. The opinion derived from such an evaluation.
2.
 - a. A critical analysis of the nature of something.
 - b. The conclusion reached by such analysis.
3. *Biology.* A brief description of the distinguishing characteristics of an organism, as for taxonomic classification.

[Greek *diagnōsis*, discernment, from *diagnōskein*, to distinguish : *dia-*, apart; see *dia-* + *gnōskein*, *gnō-*, to come to know, discern.]

Britannica



diagnosis

Identification of a disease or disorder. Diagnosis requires a medical history (including family history), a physical examination, and usually tests and diagnostic procedures (e.g., blood analysis, diagnostic imaging). A list of possible causes—the differential diagnosis—is developed and then narrowed down by further tests that eliminate or support specific possibilities.

For more information on diagnosis, visit [Britannica.com](http://www.britannica.com).

Encyclopedia



diagnosis, determination of the nature of a disease or ailment. A clinical diagnosis is based on the medical history and physical examination of the patient: it may be confirmed with X-Rays, CAT Scans (Computerized Axial Tomography), MRI (Magnetic Resonance Imaging), and other laboratory tests. Diagnosis by physical examination includes ascertaining temperature, pulse, and blood pressure and involves the use of palpation, to detect enlarged organs and other abnormalities;

<http://www.answers.com/main/ntquerv?s=diagnosis&print=true>

PAGE 28/29 * RCVD AT 11/9/2006 11:32:10 PM [Eastern Standard Time] * SVR:USPTO-EFXXRF-6/37 * DNIS:2738300 * CSID:2023935350 * DURATION (mm-ss):03-52

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prognosis

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Dictionary

*The American Heritage®
dic-tion-ar-ies*

prog-no-sis (prŏg-nō'sis) 

n., *pl.* *-ses* (-sēz).

- a. A prediction of the probable course and outcome of a disease.
- b. The likelihood of recovery from a disease.
2. A forecast or prediction: *a gloomy prognosis for economic recovery.*

[Late Latin *prognōsis*, from Greek, from *prognōskein*, to foreknow : *pro-*, before; see *pro-*² + *gignōskein*, *gnō-*, to know.]

Cancer Dictionary

THOMSON
GALE

Prognosis

The predicted outcome of a disease.

Thesaurus

HOUGHTON
MIFFLIN
COMPANY

prognosis

noun

The act of predicting: forecast, outlook, prediction, prognostication, projection. See foresight.

Health

HOUGHTON
MIFFLIN
COMPANY